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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**THE PARTIES' JOINT STATUS
REPORT FOR THE MAY 3, 2017
CASE MANAGEMENT
CONFERENCE**

1 In accordance with Paragraph G of Case Management Order No. 22 [Doc. 5007],
 2 the Parties hereby submit their Joint Status Report for the May 3, 2017 Case Management
 3 Conference.

4 **I. Discovery**

5 A. MDL Common Discovery

6 The Parties completed MDL common discovery on February 3, 2017.

7 The following depositions have been completed:

8	December 15, 2015	30(b)(6) re FDA Warning Letter
9	January 11, 2016	Kay Fuller
10	January 20, 2016	Continued 30(b)(6) re FDA Warning Letter
11	March 18, 2016	30(b)(6) re corporate structure
12	April 27, 2016	30(b)(6) re ESI systems structure
13	May 3, 2016	Murray Asch, M.D.
14	May 11, 2016	Carol Vierling
15	May 17, 2016	Anne Bynon
16	May 24, 2016	Len DeCant
17	June 2, 2016	John DeFord
18	June 9, 2016	Bret Baird
19	June 16, 2016	Robert DeLeon
20	June 17, 2016	Joe DeJohn
21	July 18, 2016	Abithal Raji-Kubba
22	July 27, 2016	Bill Little
23	July 27, 2016	Judy Ludwig
24	July 29, 2016	John Wheeler
25	August 9, 2016	Maureen Uebelacker
26	August 16, 2016	Daniel Orms
27	August 19, 2016	Mary Edwards
28	August 24, 2016	Cindi Walcott

1	August 30, 2016	30(b)(6) re REACH program
2	September 7, 2016	Steve Williamson
3	September 7, 2016	30(b)(6) re Sales/Marketing
4	September 7, 2016	Kevin Shifrin
5	September 16, 2016	Jack Sullivan
6	September 19, 2016	Brian Doherty
7	September 23, 2016	Holly Glass
8	September 29, 2016	John Van Vleet
9	October 11, 2016	Chris Ganser
10	October 18, 2016	Natalie Wong
11	November 3, 2016	Jack Sullivan (continued)
12	November 11, 2016	Robert Cortelezzi
13	December 6, 2016	David Peeler, M.D.
14	January 4, 2017	John Kaufman, M.D.
15	January 18, 2017	Michael Randall - 30(b)(6) Meridian/Denali
16	January 18, 2017	Kim Romney
17	January 19, 2017	Robert Carr - 30(b)(6) Key Opinion Leaders
18	January 20, 2017	Scott Trerotola, M.D.
19	January 24, 2017	Scott Randall
20	January 25, 2017	Gary Cohen, M.D.
21	January 26, 2017	Chad Modra - 30(b)(6) Failure Rate Thresholds
22	January 26, 2017	Anthony Venbrux, M.D.
23	January 30, 2017	Frank Lynch, M.D.
24	January 31, 2017	Mark Wilson
25	February 1, 2017	William Stavropoulos, M.D.
26	February 2, 2017	Mike Randall
27	February 2, 2017	Kevin Boyle
28		

1 B. MDL Expert Disclosure and Discovery

2 Plaintiffs made their initial disclosures of expert witnesses on March 3, 2017 and
3 their initial disclosures relating to the Meridian and Denali devices on April 7, 2017.

4 Those disclosures included the following witnesses:

5 David W. Bates, M.D., MSc

6 Rebecca Betensky, Ph.D.

7 Mark J. Eisenberg, M.D.

8 David Garcia, M.D.

9 Steven M. Hertz, M.D.

10 Sanjeeva Kalva M.D.

11 David A. Kessler, M.D.

12 Thomas Kinney, M.D., M.S.M.E.

13 Robert M. McMeeking, Ph.D., NAE, FREng, FRSE, LFASME

14 Robert O. Ritchie, Ph.D.

15 Suzanne Parisian, M.D.

16 Anne Christine Roberts, M.D.

17 Michael B. Streiff, M.D.

18 Robert L. Vogelzang, M.D.

19 Defendants made their initial disclosures of expert witnesses on April 14, 2017 and
20 their initial disclosures relating to the Meridian and Denali devices on May 12, 2017.

21 Those disclosures included the following witnesses:

22 Christine L. Brauer, Ph.D.

23 Paul Briant, Ph.D., P.E.

24 Audrey A. Fasching, Ph.D., P.E.

25 David W. Feigal, Jr., M.D., M.P.H.

26 Clement J. Grassi, M.D.

27 Mark W. Moritz, M.D.

28 Christopher S. Morris, M.D.

1 Frederick B. Rogers, M.D., FACS

2 Moni Stein, M.D., FSIR

3 Ronald A. Thisted, Ph.D.

4 Donna Bea Tillman, Ph.D., M.P.A.

5 Rebuttal disclosures are due on May 12, 2017. The deadline for completion of
6 expert discovery is July 14, 2017.

7 The Parties have begun scheduling depositions of experts and believe that they will
8 need a short extension of the discovery deadline for expert depositions. We address this
9 issue in Section III below.

10 The following depositions have been scheduled thus far:

11 May 9, 2017 David W. Bates, M.D., MSc

12 May 16, 2017 Steven M. Hertz, M.D.

13 May 17, 2017 Christopher S. Morris, M.D.

14 June 9, 2017 Robert O. Ritchie, Ph.D.

15 June 17, 2017 Thomas Kinney, M.D., M.S., M.E.

16 June 20, 2017 Sanjeeva Kalva, M.D.

17 June 21, 2017 David L. Garcia, M.D.

18 June 21, 2017 Anne Christine Roberts, M.D.

19 June 23, 2017 Rebecca Betensky, Ph.D.

20 July 6, 2017 Mark J. Eisenberg, M.D., MPH, FACC, FAHA

21 The Parties have agreed that the depositions will proceed with Plaintiffs' expert in
22 a certain discipline first and Defendants' expert in the same discipline will follow within a
23 reasonable time thereafter.

24 C. Barazza Discovery

25 The Parties have completed the depositions of the named plaintiffs.

26 The following depositions were taken:

27 October 19, 2016 Diane Washington

28 October 28, 2016 James Holt

1	November 10, 2016	Gregory Lester
2	November 16, 2016	Maria Barazza
3	November 30, 2016	Edward Mims
4	December 1, 2016	Nancy Mosher
5	December 6, 2016	Thomas Flournay
6	December 6, 2016	Delmar Lee Peck
7	December 15, 2016	Denise Tomlin
8	January 24, 2017	John Van Vleet
9	February 27, 2017	Linda Walker

10 The Parties have designated and disclosed experts regarding class certification
 11 issues, including Plaintiffs' recently designated and disclosed rebuttal expert reports.

12 D. Discovery Group I Discovery

13 The depositions of all Discovery Group 1 plaintiffs and spouse or family members
 14 have been completed. The Parties have also taken the depositions of all treating
 15 physicians allowed by CMO 21 with the exception of the implanting physician in the King
 16 case (whose deposition the Parties are still working to schedule). Plaintiffs have taken the
 17 deposition of a sales representative or supervisor in each of the Discovery Group 1 cases
 18 and completed those by April 10, 2017 in accordance with CMOs 20 and 21.

19 The following specific depositions have been completed:

20	January 25, 2017	Lisa Hyde (<i>Hyde</i>)
21	January 25, 2017	Mark Hyde (<i>Hyde</i>)
22	January 26, 2017	Justin Peterson (<i>Peterson</i>)
23	January 26, 2017	Lisa Peterson (<i>Peterson</i>)
24	January 26, 2017	Michael King (<i>King</i>)
25	January 26, 2017	Jessica King (<i>King</i>)
26	February 3, 2017	Doris Jones (<i>Jones</i>)
27	February 3, 2017	Alfred Jones, Sr. (<i>Jones</i>)
28	February 4, 2017	Joseph Mixson (<i>Mixon</i>)

1	February 4, 2017	Virginia Mixson (<i>Mixon</i>)
2	February 7, 2017	Deborah Ann Kaiser (<i>Kaiser</i>)
3	February 7, 2017	Brandy Ball (<i>Kaiser</i>)
4	February 8, 2017	Debra Mulkey (<i>Mulkey</i>)
5	February 8, 2017	Joshua Thompson (<i>Mulkey</i>)
6	February 8, 2017	Debra Ann Tinlin (<i>Tinlin</i>)
7	February 8, 2017	James Tinlin (<i>Tinlin</i>)
8	February 15, 2017	Brent Dewitt (<i>Dewitt</i>)
9	February 15, 2017	Providencia Dewitt (<i>Dewitt</i>)
10	February 16, 2017	Randy Nelson (<i>Nelson</i>)
11	February 16, 2017	Judy Nelson (<i>Nelson</i>)
12	February 20, 2017	Sherr-Una Booker (<i>Booker</i>)
13	February 20, 2017	Shomari Cottle (<i>Booker</i>)
14	February 20, 2017	Carol Kruse (<i>Kruse</i>)
15	February 20, 2017	Diane Bierre (<i>Kruse</i>)
16	March 20, 2017	Scott Karch (<i>Mulkey</i>)
17	March 21, 2017	Marcus D'Ayala, M.D. (<i>Booker</i>)
18	March 22, 2017	Salil Patel, M.D. (<i>Booker</i>)
19	March 22, 2017	Timothy McCowan, M.D. (<i>Kaiser</i>)
20	March 22, 2017	Anthony Avino, M.D. (<i>Jones</i>)
21	March 22, 2017	Keith Mallison (<i>Dewitt</i>)
22	March 23, 2017	Kirstin Nelson, M.D. (<i>Jones</i>)
23	March 23, 2017	Jay D. Goodman, M.D. (<i>Peterson</i>)
24	March 23, 2017	William Kuo, M.D. (<i>Hyde</i>)
25	March 24, 2017	Quazi Al-Tariq, M.D. (<i>Dewitt</i>)
26	March 27, 2017	Matthew Fermanich (<i>Hyde</i>)
27	March 27, 2017	David Shawn Fecher (<i>Kaiser</i>)
28	March 28, 2017	Marc Workman, M.D. (<i>Mulkey</i>)

1	March 28, 2017	Ronald Fewell, M.D. (<i>Kaiser</i>)
2	March 29, 2017	Chris Siller (<i>Mixon</i>)
3	March 29, 2017	Timothy Fischer (<i>Tinlin</i>)
4	March 31, 2017	Christopher Tinsley (<i>Kruse</i>)
5	April 3, 2017	Mark Hutchins, M.D. (<i>Kruse</i>)
6	April 3, 2017	Erin Torres Coda (<i>Nelson</i>)
7	April 4, 2017	Joshua Riebe, M.D. (<i>Tinlin</i>)
8	April 4, 2017	Shanon Smith, M.D. (<i>Kruse</i>)
9	April 5, 2017	John Weist, M.D. (<i>Peterson</i>)
10	April 5, 2017	Chad Laurich, M.D. (<i>Nelson</i>)
11	April 5, 2017	Roslyn Radee-Smith (<i>King</i>)
12	April 6, 2017	Robert Seidel, M.D. (<i>Nelson</i>)
13	April 6, 2017	David Henry, M.D. (<i>Hyde</i>)
14	April 7, 2017	Romeo Mateo, M.D. (<i>Dewitt</i>)
15	April 7, 2017	James Burks, M.D. (<i>King</i>)
16	April 7, 2017	Robert Ferrara (<i>Booker</i>)
17	April 7, 2017	Melanie Vilece Sussman (<i>Jones</i>)
18	April 10, 2017	Sandra Jean-Charles, M.D. (<i>Mixson</i>)
19	April 11, 2017	Roderick Tompkins, M.D. (<i>Mulkey</i>)
20	April 11, 2017	Anthony Goei, M.D. (<i>Mixson</i>)
21	April 11, 2017	Bill Edwards (<i>Peterson</i>)

22 **II. Bellwether Group 1 Selection**

23 In accordance with CMOs 11, 18, and 20, the Parties have made their submissions
 24 and responsive submissions to the Court regarding the selection of cases for inclusion in
 25 Bellwether Group 1. The Parties will be prepared to address their submissions and
 26 arguments in favor of those submissions at the CMC.

1 **III. Extension of Expert Discovery Deadline to July 31, 2017**

2 The Parties have conferred and jointly agree and request that the Court extend the
 3 deadline for completion of expert discovery through July 31, 2017. The present deadline
 4 is July 14, 2017. Based on the number of experts and issues and the coordination of both
 5 common and case-specific experts, the Parties have already commenced working with
 6 their experts to schedule depositions. A number of the experts will be deposed both in the
 7 MDL and on issues relevant to the medical-monitoring case (i.e. they have been
 8 designated in both cases and will be deposed in both cases). The Parties reasonably
 9 believe that they will need through the end of July to complete the discovery of the
 10 numerous experts in these cases. The extension will not impact any other deadlines
 11 presently in place.

12 The Parties will be prepared to discuss this with the Court at the CMC.

13 **IV. Bellwether Group 1 Discovery Protocols**

14 The Parties are in the process of negotiating a proposed form of CMO for
 15 discovery in Bellwether Group 1. Prior to the CMC, the Parties will submit an agreed
 16 proposed form of CMO or competing forms in the event that they do not agree on all
 17 contents of the order. The Parties will be prepared to discuss this issue at the CMC.

18 **V. Defendants' Motion for Summary Judgment**

19 In accordance with CMO 22, Defendants filed a motion for summary judgment
 20 based on preemption on March 24, 2017 and the Parties have met and conferred regarding
 21 Plaintiffs' response to the motion and need for time to prepare expert responses or to
 22 conduct other discovery. The Parties' respective positions are set forth below.

23 **Plaintiffs' Position**

24 **A. Plaintiffs Should Be Permitted to Cross-Move for Summary Judgment**
 25 **on the Law Before Embarking on Expensive and Time-Consuming**
 26 **Discovery Necessary to Controvert Many of Bard's Proffered Facts on**
 27 **Support of Its Motion.**

28 Plaintiffs have reviewed Defendants' Motion for Summary Judgment Regarding
 Preemption (the "Motion") and considered whether they need to take additional discovery

1 and seek Rule 56(d) relief in order to respond to the Motion. Bard's Motion sets forth
2 alleged "facts" in response to which Plaintiffs would want the opportunity to provide
3 expert testimony (which they contemplate will take place in the upcoming expert
4 disclosure and discovery period) and to depose the witnesses on whose lengthy affidavits
5 the Motion relies. However, rather than proceeding to a Rule 56(d) response and
6 discovery, Plaintiffs expect that this Court can resolve the Motion as a matter of law and
7 suggest a method that would allow the parties this opportunity without disturbing the
8 current discovery schedule.

9 Bard's Motion is supported by a Statement of Facts that asserts 818 individual
10 "facts" supported by two declarations with hundreds of underlying exhibits:

- 11 1) Declaration of Robert Carr -- contains 136 asserted facts and/or opinions,
12 citing 128 documents (primarily communications with the FDA);
- 13 2) Declaration of John Van Vleet -- contains 86 asserted facts and/or
14 opinion, citing 87 documents (primarily communications with the FDA).

15 Plaintiffs note that the testimony of these witnesses on the subjects in their
16 affidavits was not previously disclosed and the witnesses were not deposed regarding
17 these subjects (and Mr. Carr was not deposed at all in the MDL). Many of the alleged
18 "facts" asserted in Bard's Statement of Facts are direct or slightly modified quotes from
19 certain guidance documents, or consist of reports of submissions to the FDA and various
20 communications with numerous employees of the FDA (who Plaintiffs cannot cross-
21 examine under 21 C.F.R. § 20.1 (a-b)) spanning well over a decade.

22 As Plaintiffs advised the Court at the last CMC, Plaintiffs dispute many of the
23 "facts" Bard submits and the manner in which Bard uses the facts in its Motion. Yet, this
24 Court can and should decide preemption as a matter of law because the law on preemption
25 is decidedly against Bard's argument here. Rather than controverting Bard's statement of
26 818 alleged "facts" and addressing the two affidavits on which they are based, Plaintiffs
27 suggest a practical staged process in which Plaintiffs first present a cross-motion for
28 summary judgment on preemption as a matter of law, even assuming all of Bard's alleged

1 facts are true. If the Court agrees with Plaintiffs, there will be no need for further action.
2 However, if the Court concludes the issue cannot be decided as a matter of law against
3 Bard accepting as true all of its allegations, Plaintiffs will respond to Bard's Separate
4 Statement of Facts. By that time, expert discovery will be completed and Plaintiffs can
5 determine what if any additional discovery is necessary to controvert many of Bard's
6 statements of material fact.

7 This two-stage approach is appropriate for a variety of reasons. First, preemption
8 is traditionally an issue that courts resolve as a matter of law. *See, e.g., Medtronic, Inc. v.*
9 *Lohr*, 518 U.S. 470 (1996). Plaintiffs believe this case are not meaningfully different than
10 those adjudicated in multiple other medical device preemption cases. If the issue of
11 preemption can be resolved as a matter of law against Defendants accepting their version
12 of the facts, the parties and the Court will conserve considerable time and resources.
13 Responding to many of Bard's alleged "facts" will require Plaintiffs to elicit expert
14 opinions showing the differences between the medical device premarket approval (PMA)
15 process (for which claims are preempted) and the streamlined 510(k) clearance process—
16 (for which claims are not preempted). Additionally, expert testimony will be required to
17 explain that the FDA's process in clearing IVC filters was not out of the ordinary and that
18 many of the "extra steps" the FDA required of Bard to secure clearance were necessitated
19 by Bard's inadequate and incomplete submissions.

20 Compounding the problem, many of the documents and statements on which Bard
21 relies have evidentiary deficiencies. Most are hearsay and contain hearsay within hearsay.
22 Controverting many of Bard's alleged "facts" will involve evidentiary challenges. That
23 laborious process that can be avoided if the Court resolves the issue as a matter of law.
24 Similarly, Plaintiffs will not need to depose Mr. Carr and Mr. Van Vleet concerning the
25 hundreds of statements attributed to them and the documents on which they rely.
26 Demonstrative of the volume of evidence at issue is that a printout of Bard's Statement of
27 Facts and supporting documents is tens of thousands of pages and barely fits in 35 large
28 three-ring binders. The need to respond to all of those can be avoided by this process.

1 Plaintiffs suggest the following briefing schedule, without waiving their ability to
2 later, if necessary, controvert many of the facts Bard's Motion relies upon:

3 Plaintiffs' Response and Cross-motion for 4 Summary Judgment re Preemption (on legal 5 issues ONLY):	May 26, 2017
6 Defendants' Response and Reply (on legal 7 issues ONLY)	June 16, 2017
8 Plaintiffs' Reply re Cross-motion (on legal 9 issues ONLY)	June 30, 2017

10 Should the preemption issue not resolve through this approach, the parties can
11 complete the necessary expert and factual discovery by the current close of discovery.

12 **B. Plaintiffs' Rule 56 Application**

13 If the Court declines to follow Plaintiffs' proposed staged process, Plaintiffs
14 request the Court deny Defendants' Motion outright or, at a minimum, allow Plaintiffs the
15 opportunity to conduct the limited Rule 56(d) discovery outlined below.¹

16 Bard's Motion is premised upon numerous alleged "undisputed facts" that purport
17 to distinguish the process by which Bard secured FDA 510(k) clearance for its IV filters
18 from a traditional 510(k) process. Based on its narrative, Bard suggests that Plaintiffs'
19 claims are federally preempted because it claims Bard's clearance was more akin to the
20 premarket approval (PMA) process used by the FDA for new medical devices brought to
21 market. But many of Bard's alleged "undisputed facts" are contested, actually just
22 conclusions and opinions (not facts), and based upon hearsay and other forms of
23 inadmissible evidence.

24 ¹ Plaintiffs make this application without waiving the right to oppose Defendants' motion
25 on any grounds including, without limitation, its argument that the evidence in documents
26 already obtained raises genuine, triable issues of material fact sufficient to defeat
27 Defendants' Motion, or, that Defendants fail as a matter of law to carry its initial,
28 threshold burden for purposes of summary judgment under Fed. R. Civ. P. 56 based on the
numerous procedural and substantive deficiencies in its Motion.

1 If required to respond to Bard's Statement of Facts, Plaintiffs would be required to
 2 engage in discovery (including expert disclosures) to address: (1) the PMA and 510(k)
 3 processes; (2) "special controls" applicable to filter products and other Class II devices;
 4 (3) Bard's interactions with the FDA; (4) the actual FDA clearance process for Bard's
 5 IVC filters. Specifically, Plaintiffs will need to opportunity to complete expert disclosure
 6 and discovery, which will include these issues. Plaintiffs will also need to depose the two
 7 witnesses who provided declarations in support of Bard's SOF, Messrs. Carr and Van
 8 Vleet.

9 1. Legal Standard for Rule 56(D) Applications

10 Rule 56(d) provides a device for litigants to avoid summary judgment when there
 11 are insufficiencies in the discovery process to develop affirmative evidence to oppose a
 12 dispositive motion. *Burlington Northern Santa Fe R. Co. v. Assiniboine and Sioux Tribes*
 13 *of Fort Peck Reservation*, 323 F.3d 767, 773 (9th Cir. 2003). "The general principle of
 14 Rule 56(f)² is that 'summary judgment should be refused where the nonmoving party has
 15 not had the opportunity to discover information that is essential to his opposition.'" *Price*
 16 *v. Western Resources, Inc.*, 232 F.3d 779, 793 (10th Cir.2000) (quoting *Anderson v.*
 17 *Liberty Lobby*, 477 U.S. 242, 250 n.5, 106 S. Ct. 2505 (1986)).

18 Rule of Civil Procedure 56(d) provides "a device for litigants to avoid summary
 19 judgment when they have not had sufficient time to develop affirmative evidence." *Slama*
 20 *v. City of Madera*, 2012 WL 1067198, at *1–2 (E.D. Cal. Mar. 28, 2012)(citing *United*
 21 *States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1000 (9th Cir.2002)).

22 Rule 56(d) reads:

23 *When Facts Are Unavailable to the Nonmovant.* If a nonmovant
 24 shows by affidavit or declaration that, for specified reasons, it cannot
 25 present facts essential to justify its opposition, the court may:
 26 (1) defer considering the motion or deny it;
 (2) allow time to obtain affidavits or declarations or to take
 discovery; or
 (3) issue any other appropriate order.

27
 28 ² Effective December 1, 2010, the Federal Rules of Civil Procedure were amended such
 that the general provisions of Rule 56(f) are now located at amended Rule 56(d).

1 Fed. R. Civ. Pro. 56(d).

2 Pursuant to Rule 56(d), this Court has the discretion to deny or continue a motion
3 for summary judgment “if a party opposing the motion shows by affidavit that, for
4 specified reasons, it cannot present facts essential to justify its position.” *Cal. Union. Ins.*
5 *Co. v. American Diversified Sav. Bank*, 914 F.2d 1271 (9th Cir.1990).

6 To secure Rule 56(d) relief, the “requesting party must show: (1) it has set forth in
7 affidavit form the specific facts it hopes to elicit from further discovery; (2) the facts
8 sought exist; [and] (3) the sought-after facts are essential to oppose summary judgment.”
9 *Family Home and Fin. Ctr., Inc. v. Fed. Home Loan Mortg. Corp.*, 525 F.3d 822, 827 (9th
10 Cir.2008).

11 The party seeking relief should explain in its affidavit why those facts would
12 preclude summary judgment. *See, Tatum v. City and County of San Francisco*, 441 F.3d
13 1090, 1100 (9th Cir. 2006); *California v. Campbell*, 138 F.3d 772, 779 (9th Cir. 1998).

14 2. A Rule 56(D)(2) Continuance Is Necessary Here.

15 a. Plaintiffs’ Rule 56(d)(2) Affidavit

16 Plaintiffs have set forth in the form of a sworn Rule 56(d) compliant affidavit the
17 additional facts they seek to discover to oppose Bard’s Motion. Those facts consist
18 largely of additional expert opinions and the depositions of the two Bard witnesses who
19 provided declaration in support of Bard’s Statement of Facts. As set forth in the affidavit,
20 prior to Bard filing its Motion, there was no reason for Plaintiffs to anticipate that the
21 discovery sought in the affidavit was necessary, and they focused their discovery effort on
22 other areas of the case.

23 b. The Facts Plaintiffs Seek to Discover Exist

24 Plaintiffs seek to be able to disclose expert testimony and opinions regarding (1)
25 the PMA and 510(k) processes; (2) “special controls” applicable to filter products and
26 other Class II devices; (3) Bard’s interactions with the FDA; (4) the actual FDA clearance
27 process for Bard’s IVC filters. Plaintiffs have experts who are qualified and available to
28 provide such testimony and opinions.

1 Plaintiffs also seek to depose witnesses Carr and Van Vleet. Those witnesses
 2 presumably are available for depositions limited to the declarations they have authored in
 3 support of Bard's Motion.

4 c. The Facts Sought Are Essential to Oppose Summary
 5 Judgment

6 If the Court does not conclude that Bard's preemption argument fails as a matter of
 7 law, Plaintiffs will need the ability to disclose expert testimony regarding the FDA
 8 regulation activities, which will controvert the core of Bard's Motion.

9 Specifically, the following expert testimony will controvert the core of Bard's
 10 preemption argument:

- 11 • Regulatory processes related to the FDA's PMA process;
- 12 • Regulatory processes related to the FDA's 510(k) process, specifically as to the
 13 issues of special controls and the relevant statutory and regulatory 510(k)
 14 framework. (Def. Mot., at 17);
- 15 • That special controls and device specific "requirements" do not rise to the level
 16 of PMA and are consistent with traditional 510(k) clearance. (Def. Mot, at 18);
- 17 • IVC Filters are not unique nor is the 510(k) process for them different than
 18 "most devices brought to the market under 510(k) – even after the SMDA". *Id.*;
- 19 • Bard's actual 510(k) clearance process for the subject devices, including the
 20 extent to which FDA requests for clarification and action by Bard were not out
 21 of the ordinary and were necessitated by deficiencies in Bard's formal 510(k)
 22 submissions;
- 23 • The 510(k) clearance process does not apply differently to filters.

24 In addition, Plaintiffs must respond to Bard's mischaracterizations and inaccurate
 25 representations of regulatory processes, which are not factual but based on inappropriate
 26 conclusions. For example, Bard makes sweeping assertions that the MDA has been so
 27 overhauled that none of Plaintiffs' claims survive a federal preemption analysis. Mot. at
 28

1 17-18. Plaintiffs should be allowed to challenge such drastic claims through expert
2 testimony, particularly given the novelty of Bard's preemption arguments.

3 Additionally, Bard's Motion relies on two declarations of corporate officers that
4 contain characterizations of regulatory documents and processes. Although Bard insisted
5 it would not rely on expert testimony for its Motion, it has drafted its employees to stand
6 in the shoes of expert witnesses making allegedly factual yet conclusory statements and
7 opinions about the regulatory process. Plaintiffs are entitled to examine these witnesses
8 on the foundation for their proffered facts and opinions. Plaintiffs anticipate that such
9 discovery will expose the foundational and other deficiencies of Bard's alleged facts - that
10 are not only disputed but inadmissible as evidence.

11 3. Rule 56(D)(1) Denial of Bard's Motion Is Also Appropriate.

12 Many of Bard's purported "facts" are inadmissible hearsay statements between
13 Bard and FDA representatives. Moreover, Plaintiffs have no means of challenging Bard's
14 characterization of these conversations. Plaintiffs can neither cross-examine nor
15 otherwise conduct discovery directed at any employee of the FDA as to the agency's
16 actions, inactions, processes, etc. *See* 21 C.F.R. § 20.1(a-b). In virtually every instance of
17 communications with FDA set forth in Bard's moving papers there exists uncertainty
18 about the factual basis upon which FDA expressed concern or requested additional
19 information and the rationale for FDA's action that followed. Moreover, it is impossible
20 to determine—because Plaintiffs cannot ask the FDA personnel involved—whether
21 additional information possessed by Bard should have been produced to the FDA and
22 what effect such concealed information would have had on the 510(k) process.

23 In short, Plaintiffs can neither verify the truth of the hearsay FDA statements and
24 documents nor probe whether what Bard was asked to do as part of its 510(k) filter
25 clearance was out of the ordinary in any respect or merely the result of Bard not being
26 thorough or complete in its initial submissions. This is hugely prejudicial to Plaintiffs
27 because the premise of Bard's preemption argument is that the 510(k) clearance process
28

1 for its IVC filters was more onerous and extensive than other 510(k) medical device
2 clearances.

3 Moreover, even if Plaintiffs could theoretically depose current or former FDA
4 employees with whom Bard had the communications relevant to Bard's Motion, the time
5 and cost of such discovery would create undue and unnecessary delay in these
6 proceedings, likely pushing the schedule for dispositive motions towards the end of the
7 year and delaying bellwether trials until sometime in 2018.

8 Bard's preemption is inherently flawed because ultimately the relevance of FDA-
9 related evidence is tenuous at best. Despite Defendants' arguments, "[u]nder the Federal
10 Food, Drug, and Cosmetic Act, a manufacturer seeking to market a new medical device
11 may attempt to bypass the FDA's normal premarket approval process by submitting a '§
12 510(k) notification.'" *Huskey v. Ethicon, Inc.*, 848 F.3d 151, 160 (4th Cir. 2017) (citing
13 *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996)). It is well-established that the 510(k)
14 process only "tangentially" examines the safety of the product going through the process.
15 *Lohr*, 518 U.S. at 493-94 ("Thus, even though the FDA may well examine § 510(k)
16 applications for Class III devices with a concern for the safety and effectiveness of the
17 device, it did not 'require' Medtronic's pacemaker to take any particular form for any
18 particular reason; the agency simply allowed the pacemaker, as a device substantially
19 equivalent to one that existed before 1976, to be marketed without running the gauntlet of
20 the PMA process.") (internal citation omitted); *Cisson v. C.R. Bard Inc. (In re C.R. Bard,*
21 *Inc.)*, 810 F. 3d 919, 922 (4th Cir. 2016). That is why FDA clearance of a medical device
22 via the 510(k) process has limited probative value and admission of such evidence risks
23 confusing juries by creating, inter alia, a battle of experts over alleged "robustness of the
24 501(k) process's safety examinations" and proffering "bald assertions by the FDA" as to
25 such compliance has been rejected as highly probative of safety. *Huskey*, 848 F.3d at 160
26 (citing *Cisson*, 810 F.3d at 921-22).

Defendants' Position

During the last conference, the parties, and the Court, addressed the Defendants' desire to file a motion for summary judgment premised on a preemption argument. In Case Management Order No. 22, the Court instructed the Plaintiffs to file an affidavit or declaration that complies with Rule 56(d) of the Federal Rules of Civil Procedure with this submission if they considered further factual or expert discovery necessary (Doc. 5007). Rather than make such a submission, however, the Plaintiffs have instead proposed filing their own cross motion suggesting the Court can consider the preemption issue "as a matter of law," without considering the factual support offered by the Defendants. The Defendants object to this proposal, believing that such a procedure would be unworkable, unnecessary, and a waste of resources for both the Court and the parties.

As a threshold matter, the Plaintiffs misconstrue the Defendants' past acknowledgement that the motion can be decided "as a matter of law." Bard was not suggesting the motion could be decided without an assessment of the factual history of the device. Rather, Bard was referencing the Plaintiffs' claim that expert testimony would be necessary to oppose the motion.¹ The controlling question is whether the FDA – via its regulations, its guidance documents, and its oversight activities – imposed device-specific requirements on Bard's IVC filters regarding their safety and effectiveness. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 787 (D. Ariz. 2014). That is a question of law. *See Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 446 (D.N.J. 2003) (rejecting expert testimony because "whether the FDA's approval of a [device] imposes requirements on a particular device is a question of law to be determined by the Court."). Multiple courts have likewise rejected expert testimony on the legal effect of regulations

¹ Much of the discovery the Plaintiffs claim to need in order to respond to Bard's motion involves expert testimony regarding the 510(k) process, special controls, and similar issues. In effect, the Plaintiffs appear to be suggesting the right to present expert testimony concerning the legal import of the FDA's regulatory oversight of IVC filters.

1 or regulatory activity. *See, e.g., Livingston v. Wyeth, Inc.*, No. 1:03CV00919, 2006 WL
2 2129794, at *6 (M.D.N.C. July 28, 2006); *United States v. Caputo*, 374 F. Supp. 2d 632,
3 646 (N.D. Ill. 2005); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546-47
4 (S.D.N.Y. 2004); *Smith v. Wyeth-Ayerst Labs., Inc.*, 278 F. Supp. 2d 684, 702 (W.D.N.C.
5 2003); *Moses v. Danek Medical, Inc.*, No. CV-S-95-512PMPRLH, 1998 WL 34024164, at
6 *3 (D. Nev. Dec. 9, 1998); *Purnell v. United States*, No. CIV. A. No. 86-4475, 1987 WL
7 13790, at *3 (E.D. Pa. 1987). As the Seventh Circuit succinctly noted, “[t]he only legal
8 expert in a federal courtroom is the judge.” *Caputo v. United States*, 517 F.3d 935, 942
9 (7th Cir. 2008).

10 Here, however, the Plaintiffs appear to be suggesting the motion can be decided as
11 a matter of law because the facts need not be analyzed. Apparently, they want to file their
12 own motion for summary judgment arguing that preemption is categorically foreclosed
13 with a 510(k) device, arguing that “even assuming all of Bard’s alleged facts are true” and
14 “accepting [Defendants’] version of the facts,” their claims are not preempted. That
15 position is contrary to the law. Even in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the
16 case on which the Plaintiffs rely, the deciding vote Justice Breyer noted in his concurrence
17 that federal law “will sometimes pre-empt a state-law tort suit” even with a 510(k) device.
18 518 U.S. at 503. Other courts have agreed. *See Papike v. Tambrands, Inc.*, 107 F.3d 737,
19 742 (9th Cir. 1997) (“This result is entirely consistent with *Medtronic*, which did not
20 involve device-specific federal requirements.”). Accordingly, the Defendants believe a
21 preliminary motion on the theoretical application of preemption on a 510(k) product,
22 devoid of the factual context, would be a wasteful exercise. Instead, because the
23 preemptive effect of the FDA’s regulatory oversight does not depend simply on the
24 regulatory pathway (PMA versus 510(k)), but rather on the special controls imposed by
25 the agency, the specific factual circumstances of the FDA’s regulatory activity will in fact
26 be determinative of the legal issue.

27 Bard therefore believes the process should proceed as the Court outlined in CMO
28 No. 22. The Plaintiffs state that they are going to file a Rule 56(d) request as

1 contemplated by the Court’s order, but despite repeated requests, they have declined to
2 share that request with the Defendants.² As a consequence, the only information available
3 to Bard at this juncture is the generalized statements contained in this submission. Such
4 descriptions do not satisfy the requirements for a Rule 56(d) request. An application
5 under that provision must “make clear what information is sought and how it would
6 preclude summary judgment.” *Nicholas v. Wallenstein*, 266 F.3d 1083, 1088-89 (9th Cir.
7 2001). A general or conclusory assertion that additional discovery is needed – as the
8 Plaintiffs have done here – is insufficient. *See, e.g., Tatum v. City and County of San*
9 *Francisco*, 441 F.3d 1090, 1100 (9th Cir. 2006) (affirming summary judgment and
10 specifically approving district court’s refusal to grant Rule 56(d) relief because non-
11 movant “did not identify the specific facts that further discovery would have revealed or
12 explain why those facts would have precluded summary judgment”).

13 Nor does the Plaintiffs’ description of facts they allegedly say they need – even if
14 formalized in an affidavit – appear to be an appropriate use of the Rule 56(d) procedure.
15 Fact discovery on the regulatory history of Bard’s IVC filters took place during the year-
16 long fact discovery period that concluded February 3, 2017. Throughout that period, the
17 Plaintiffs had notice that preemption was an issue, since the defense was pled in Bard’s
18 master answer. (*See* Doc. 366 at Defense No. 7).³ Also, during that period, the Plaintiffs
19 deposed both of the declarants multiple times, Mr. Carr twice as a Rule 30(b)(6)
20 representative and Mr. Van Vleet twice (once as a corporate representative and once as an
21 individual). They also deposed Mary Edwards, who was a former Vice President of
22 Regulatory Affairs (the position presently held by Mr. Van Vleet). Prior to the MDL, the
23 Plaintiffs’ co-lead counsel took a six-hour deposition of Shari Allen, another regulatory
24 executive at the company. Additionally, they have access to the transcripts of ten other
25

26 ² Because the Plaintiffs have not shared their anticipated filing with the Defendants, Bard
27 has not been afforded a meaningful opportunity to respond. Bard therefore asks for the
28 opportunity to respond to the details of the Rule 56(d) request once it is provided to them.

³ Hence, contrary to Plaintiffs’ assertion, they did in fact have reason to “anticipate” that
the discovery they are now seeking would be necessary.

1 depositions taken of Mr. Carr prior to the MDL. Finally, the Plaintiffs took a 30(b)(6)
2 deposition regarding the Meridian® and Denali® Filters, and many of the topics
3 concerned the regulatory history of those devices.

4 Rule 56(d) is not applicable in these circumstances. “Rule 56(d) does not reopen
5 discovery; rather it forestalls ruling on a motion for summary judgment in cases where
6 discovery is still open and provides the prospect of defeating summary judgment.”
7 *Dumas v. Bangi*, No. 1:12-CV-01355-LJO, 2014 WL 3844775, at *2 (E.D. Cal. Jan 23,
8 2014); accord *Lexington Ins. Co. v. Scott Homes Multifamily, Inc.*, No. CV-12-02119-
9 PHX-JAT, 2015 WL 751204, at *5 (D. Ariz. Feb 23, 2015). The rule is not a vehicle to
10 extend discovery automatically whenever a party is faced with a summary judgment
11 motion. Instead, it “provides a device for litigants to avoid summary judgment when they
12 have not had sufficient time to develop affirmative evidence.” *United States v. Kitsap*
13 *Physicians Serv.*, 314 F.3d 995, 1000 (9th Cir. 2002); see also *Roberts v. McAfee, Inc.*,
14 660 F.3d 1156, 1169 (9th Cir. 2011) (“[T]his rule requires discovery only where the non-
15 moving party has not had the opportunity to discover information that is essential to its
16 opposition.” (emphasis added)); *Caravan Mobile Home Sales, Inc. v. Lehman Bros. Kuhn*
17 *Loeb, Inc.*, 769 F.2d 561 (9th Cir. 1985) (affirming district court’s denial of Rule 56(d)
18 relief (formerly 56(f)) where nonmoving party had been allowed ample discovery and had
19 taken almost 400 pages of deposition testimony from the witness whom the party sought
20 to depose).

21 Finally, the Plaintiffs raise evidentiary concerns, including hearsay, regarding the
22 affidavits and facts submitted by Bard in support of its motion. The Plaintiffs’ argument is
23 premature at this stage. The Plaintiffs are free to raise evidentiary objections to Bard’s
24 motion when they file their response brief. See Fed. R. Civ. Proc. 56(c)(2).

25 In sum, the Plaintiffs’ “preview” of any Rule 56(d) declaration they may eventually
26 file suggests that the submission would not satisfy the requirements of that provision. If
27 the Plaintiffs want to circumvent the fact discovery deadline and expand their opportunity
28 to conduct fact discovery beyond the year-long discovery period already afforded them,

1 they should be required to comply with Rule 56(d) as written and as interpreted by the
2 Ninth Circuit.

3 **VI. Schedule for *Daubert* Motions and Discovery Group 1 Summary Judgment**
4 **Motions**

5 In CMO 18, this Court stated that its intention was to set a schedule that would
6 permit the completion of bellwether discovery and motion practice in time to hold the first
7 bellwether trial in the Fall of 2017.

8 On the assumption that the Court agrees to the extension of the close of expert
9 discovery to July 31, 2017, the Parties propose the following schedule for *Daubert*
10 motions and Discovery Group 1 case-specific summary judgment motions (if any):

11 *Daubert* and summary judgment motions due: August 21, 2017

12 Plaintiffs' responses due: September 15, 2017

13 Reply briefs due: September 29, 2017

14 **VII. Plaintiffs' Proposal for a Science Day**

15 **Plaintiffs' Position:**

16 Plaintiffs propose that the Court allow the Parties to hold a "science day" at which
17 each side can present the Court with information from doctors, scientists, and other
18 experts regarding Bard's IVC filters, the alleged science and medicine behind them, and
19 the Parties' competing positions regarding the safety and efficacy of the devices and what
20 will be at issue in the bellwether trials. Plaintiffs suggest that such a day makes sense
21 after the completion of expert discovery and before this Court hearing and deciding
22 *Daubert* and summary judgment motions.

23 Plaintiffs disagree with Defendants' suggested time limits. Because there are
24 multiple devices and design/complication issues, Plaintiffs submit that 75-90 minutes per
25 side is more appropriate.

26 **Defendants' Position:**

27 The Defendants will be happy to participate in a "science day" if the Court believes
28 the exercise will be beneficial. From past experience, the Defendants believe 45-60

1 minute presentations by both sides (perhaps made in conjunction with a regularly
2 scheduled case management conference) are the most efficient means of accomplishing
3 the aims of a "science day."

4 **VIII. Timing of Remand of Mature Cases**

5 **Plaintiffs' Position:**

6 Plaintiffs request that the Court address the timing of remand of the mature cases
7 when it determines the schedule for briefing and resolution of *Daubert* issues. As the
8 Court noted in CMO 19, it will handle common expert disclosures and *Daubert* motions
9 for those experts. However, once this Court has made any such rulings, those cases will
10 be ready for remand. Plaintiffs would like to include the timing of the remand of the
11 mature case in the schedule relating to the *Daubert* motions and resolution of the other
12 common matters in this MDL.

13 Once the Court renders its ruling on *Daubert* motions, this Court will remand the
14 ten cases that have been identified as "mature/early remand cases" to the transferor courts
15 for further pre-trial and trial proceedings, and the parties will be able to use the new fact
16 and expert discovery taken in this MDL.

17 **Defendants' Position:**

18 This same issue was raised by the Plaintiffs at the last case management
19 conference, and addressed by the Court in Case Management Order No. 19 [Doc 4311].
20 As the Plaintiffs acknowledge, the Court is going to handle common expert disclosures
21 and *Daubert* motions in the context of this MDL. Once the Court issues rulings in
22 *Daubert* motions, the parties and the Court can discuss a procedure for the prompt remand
23 of the cases. However, the Defendants do not see how a more specific schedule can be
24 established at this juncture, since the timing of any remands will be linked to the date of
25 the Court's ruling on *Daubert* motions, and that date cannot be determined in advance.

26 **IX. Motion to Disqualify One Plaintiffs' Expert**

27 The defendants have recently filed a motion to disqualify one of the plaintiffs'
28 experts, Dr. Thomas Kinney. The motion is premised on (1) the fact that Dr. Kinney

1 previously consulted with the defendants as an expert witness in filter cases, and (2) the
2 fact that Dr. Kinney consulted with Bard Peripheral Vascular, Inc. for a number of years
3 on a wide variety of filter-related projects, including animal testing of prototype devices,
4 physician training, and the analysis of complication data. The defendants maintain that
5 Dr. Kinney had access to confidential data and litigation strategies as a result of that work,
6 and in fact was a signatory to various confidentiality agreements.

7 Plaintiffs have consulted and discussed with Dr. Kinney his prior association with
8 Bard and both Dr. Kinney and Plaintiffs have concluded that prior affiliation, some ten
9 years ago, did not expose Dr. Kinney to information that would disqualify him in this
10 lawsuit or that there is any conflict created by the report and opinions he has issued in this
11 suit. Plaintiffs will respond to Defendants' motion.

12 **X. Expert Discovery in Barazza**

13 Defendants' Position

14 The Plaintiffs designated their rebuttal experts in the *Barazza* putative class action
15 on Friday, April 21st. The following Monday (April 24th), Bard promptly requested
16 deposition dates for one of the newly disclosed experts (Dr. Kush R. Desai) to be
17 completed prior to the May 19th deadline for all discovery in the Barazza case. Despite
18 multiple follow-up inquiries by Bard (given the short time frame available), the Plaintiffs
19 have not responded. Bard is becoming concerned about completing discovery by the
20 deadline if Plaintiffs delay any further in providing a date for that deposition.

21 Plaintiffs' Position

22 Plaintiffs have been working diligently to schedule the depositions of numerous
23 experts, including Dr. Desai. Plaintiffs will continue to work to schedule these
24 depositions timely and are working to obtain dates from Dr. Desai. Plaintiffs have not
25 received dates for Defendants' experts' depositions in the MDL or for the *Barazza* case
26 but do not believe it is necessary to take up this Court's time with individual deposition
27 scheduling issues.
28

Respectfully submitted this 28th day of April 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on April. 28, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Deborah Yanazzo